K132848

510(k) Summary in accordance with 21 CFR 807.92

Proprietary Name:	**Piezosurgery**
FLEX Type of 510(k) submission:	
Traditional	
Date of Submission:	September 5, 2013
Manufacturer:	Mectron Spa Via Loreto, 15, 16042 Carasco - (GE) Italy
FDA Registration Number:	3003933619
510(k) Owner:	Mectron Spa Via Loreto, 15, 16042 Carasco - (GE) Italy
510(k) Contact:	Roger Gray VP, Quality and Regulatory Donawa Lifescience Consulting Piazza Albania, 10, 00153 Rome, Italy Tel: +39 06 578 2665 Fax: +39 06 574 3786
Common Name:	Bone cutting instrument and accessories
Classification Regulation:	21 CFR 888.4850 Sonic surgical instrument and accessories/attachments.
Product Codes:	JDX, DZI, ERL, HBE, HWE
Class:	Class II

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Predicate devices: The Substantial Equivalence of the subject device of this submission is based on the predicate devices listed in Table 5.1.

Table 5.1: Predicate devices

Trade Name	Manufacturer	Product Code/s	510(k) Number	Decision Date
Piezosurgery Medical	MECTRON Spa	JDX, DZI, ERL, HBE, HWE	K083284	April 8, 2009
Piezoelectric System	SATELEC-ACTEON Group	JDX, DZI, ERL, HBE, HWE	K100410	April 28, 2010

Intended use/Indications for Use:
Piezosurgery FLEX is an ultrasonic surgical system consisting of handpieces and associated tips for cutting bone, osteotomy, osteoplasty and drilling in variety of surgical procedures, including but not limited to otolaryngological, oral/maxillofacial, hand, foot, neurosurgical, spine, and plastic/reconstructive surgery. It may also be used with endoscopic visual assistance to perform the above listed procedures.

Device Description:
Piezosurgery FLEX is a piezoelectric ultrasonic device that uses ultrasonic energy to generate mechanical micro-vibration of tip inserts intended for bone cutting. The device consists of a base control unit with integrated peristaltic pump, a sterilizable handpiece with connecting cord, a range of sterile, single use tip inserts, a torque wrench, a foot-pedal, an irrigation set, and other minor attachments.
The console is equipped with a touch panel that allows the surgeon to control device operation. The control panel also provides monitoring information, by means icons, in case of malfunction of the device. Inside the console are located the ultrasonic generator, the electrical power supply module and the micro-processor electronic board that controls and supervises the functional parameters of the device. The console is connected to mains power by an electrical cord, and includes connectors for the handpiece and for the foot-pedal. The console incorporates a peristaltic pump which provides, through the irrigation tubing set, a sterile fluid supply to the surgical site. Ultrasonic power and irrigation flow to the handpiece are simultaneously activated by pressing the foot-pedal. The handpiece contains a piezoelectric ultrasonic transducer which attaches to the generator (inside the console) by a cable at one end of the handpiece. Tip inserts are attached to the other end of the handpiece.

The touch panel of the console allows the operator to set the treatment parameters, as follows:
- Seven levels of power;
- Six levels of irrigation;
- Three ultrasonic output modes;
- The pump function.

The Piezosurgery FLEX uses piezoelectric ultrasonic technology to generate mechanical micro-vibrations of the tip insert connected to the handpiece, the piezoelectric transducer converting the electrical voltage supplied by the ultrasonic generator into mechanical energy that induces vibration of the tip insert at the resonant frequency of the tip insert.

Technological characteristics:
The technological characteristics of the Piezosurgery Flex are very similar or identical to the predicate devices. Piezosurgery FLEX offers a simpler, lower cost alternative to the predicate devices, however, having a single peristaltic pump and handpiece instead of the two pumps and handpieces that are included with the predicate devices. Piezosurgery FLEX also offers users three output modes instead of the four modes available in the predicate devices. For the user interface, Piezosurgery FLEX has a touch panel, whereas the predicate devices incorporate an LCD touch screen. The operational ultrasonic frequency range has been extended in Piezosurgery FLEX to 24 - 36 kHz, from 24 - 29.5 kHz in one predicate device and approximately 28 kHz in the other predicate device. The footswitch in one predicate device offers a wider range of operational options that in Piezosurgery FLEX.

None of these technological differences between Piezosurgery Flex and the predicate devices has any significant effect on the safety and effectiveness of the subject device.

Non-clinical testing:

Non clinical testing of the device components covered by this 510(k) submission includes:

- Testing to confirm compliance with the safety requirements of standard IEC 60601-1
- Testing to confirm compliance with EMC requirements of standard EN 60601-1-2

Substantial Equivalence

The data presented in this submission demonstrate the similarities in the intended use/indications of use and technology between the Piezosurgery Flex and the referenced predicate devices, and thus supports a finding of substantial equivalence between the subject device and the predicate devices which are already in commercial distribution in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 29, 2013

MECTRON SPA
% Mr. Roger Gray
Donawa Lifescience Consulting Srl
Piazza Albania, 10
Rome 00153
ITALY

Re: K132848
Trade/Device Name: Piezosurgery FLEX
Regulation Number: 21 CFR 888.4580
Regulation Name: Sonic surgical instrument and accessories/attachments
Regulatory Class: Class II
Product Code: JDX
Dated: September 26, 2013
Received: September 30, 2013

Dear Mr. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132848

Device Name: Piezosurgery FLEX

Indications For Use: The Piezosurgery FLEX is an ultrasonic surgical system consisting of handpieces and associated tips for cutting bone, osteotomy, osteoplasty and drilling in variety of surgical procedures, including but not limited to otolaryngological, oral/maxillofacial, hand, foot, neurosurgical, spine, and paalstic/reconstructive surgery.It may also be used with endoscopic visual assistance to perform the above listed procedures.

Prescription Use __X_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Binita S. Ashar -S
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(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number _K132848_____